

Notice of Allowability

Application No.

09/836,627

Applicant(s)

SCOTT ET AL.

Examiner

Art Unit

Humera N. Sheikh

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 16 November 2005.
2. ☒ The allowed claim(s) is/are 1-21, 24, 25 and 29-33.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

7. ☒ The Drawings filed 04/17/2001 are accepted by the Examiner.

Attachment(s)

- | | |
|---|--|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input checked="" type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date <u>2/6/06</u> . |
| 3. <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____ | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

DETAILED ACTION

Status of the Application

Receipt of the Request for Continued Examination (RCE) under 37 C.F.R. §1.114, the amendment and Applicant's Arguments/Remarks, all filed 11/16/05 is acknowledged.

Claims 1-21, 24, 25 and 29-33 are pending in this action. Claims 1 and 32 have been amended. Claims 22-23 and 26-28 have been cancelled. Claims 1-21, 24, 25 and 29-33 are allowed.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/16/05 has been entered.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Rosemary M. Miano on February 02, 2006.

The application has been amended as follows:

In the Specification:

On page 1, beginning with the first line after the title, the phrase, **“This application is a Continuation of Application No. 09/396,225 filed September 15, 1999, now abandoned, which claims benefit of Provisional Application No. 60/102,017 filed September 28, 1998”** has been added.

On page 2, line 11, the comma (,) after the word ‘UK)’ has been replaced with a period (.).

On page 2, line 10, after the term ‘S100’, the term **“(Roehm GmbH, Darmstadt, Germany)”** has been added.

On page 2, line 12, after the term ‘L100’, the term **“(Roehm GmbH, Darmstadt, Germany)”** has been added.

On page 2, line 13, after the term ‘Claversal®’, the phrase **“(available from GlaxoSmithKline, Madrid Spain)”** has been added.

On page 2, line 13, after the term ‘Salofalk®’, the phrase **“(Dr. Falk Pharma GmbH, Freiburg, Germany)”** has been added.

In the Claims:

In claims 17 and 18, after the word 'per', the term 'cm2' has been changed to "cm²".

Claim 24 has been renumbered as claim 22.

Claim 25 has been renumbered as claim 23 and is dependent on claim 22 (originally filed claim 24).

Claim 33 has been renumbered as claim 24 and is dependent on claim 22 (originally filed claim 24).

Claim 29 has been renumbered as claim 25.

Claim 30 has been renumbered as claim 26.

Claim 31 has been renumbered as claim 27.

Claim 32 has been renumbered as claim 28.

In the Abstract:

The heading entitled 'Summary' has been changed to '**Abstract**'.

Allowable Subject Matter

Claims 1-21, 24, 25 and 29-33 are allowed.

The following is an examiner's statement of reasons for allowance:

The primary reasons for allowance are that the prior art (Hatano *et al.* – EP 0 754 452 A2. & Watts – WO 95/35100) do not disclose nor teach the instantly claimed drug delivery

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composition which consists essentially of a coated hydroxypropylmethyl cellulose (HPMC) capsule comprising a single aqueous coating thereon. The prior art also fails to disclose or teach a drug delivery composition consisting essentially of a coated HPMC capsule that does not release drug from the capsule into the stomach. The prior art fails to teach singly coated capsules. In contrast, the prior art (Hatano *et al.* '452) teaches away from singly coated capsules and teaches a capsule requiring multiple coatings (at least two) to be used thereon. More specifically, Hatano *et al.* '452 teach that their capsule must be coated with a polymer film soluble at low pH and an enteric coating film (see pg. 3, lines 7-10; and pg. 9, lines 3-7 of Hatano *et al.*). The secondary reference of Watts '100 does not remedy the deficiencies of the primary reference. Watts '100 is limited to injection moulded starch capsules containing multiple coatings and does not include HPMC capsules provided with a single coating. There is no teaching or suggestion or motivation to employ an HPMC capsule with a single coating as claimed.

The instant invention demonstrates an improvement over prior art formulations because it overcomes disadvantages of the commonly employed hard gelatin capsules to achieve enteric or colonic delivery, with the use of hydroxypropylmethyl cellulose capsules. The instant invention, which provides for an enteric-coated HPMC capsule provides for superior properties than enteric-coated gelatin capsules, such as much higher resistance against acid solutions. Particular advantages of the instant HPMC capsule is that it provides for a slower drug release profile in acidic media and fast release at a pH of 5 and above. Additionally, the HPMC capsules are cost-effective and easy to manufacture and can readily be filled on standard capsule filling machines.

Thus, in view of the improvements demonstrated by the instant invention and the lack of teachings of the prior art to provide for a singly coated HPMC capsule, the instant invention is rendered non-obvious and patentable over the cited art of record.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday through Friday from 8:00A.M. to 5:30P.M., alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Humera N. Sheikh

Patent Examiner

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February 06, 2006

Humera N. Sheikh
TC-1600

hns